physician contractors and employees during the time they furnish services to patients of the group practice that are furnished through the group and are billed in the name of the group.

Patient care services means any tasks performed by a group practice member that address the medical needs of specific patients, regardless of whether they involve direct patient encounters. They can include, for example, the services of physicians who do not directly treat patients, time spent by a physician consulting with other physicians, or time spent reviewing laboratory tests.

Physician incentive plan means any compensation arrangement between an entity and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished with respect to individuals enrolled with the entity.

Plan of care means the establishment by a physician of a course of diagnosis or treatment (or both) for a particular patient, including the ordering of items or services.

Referral—

(1) Means either of the following:

(i) Except as provided in paragraph (2) of this definition, the request by a physician for, or ordering of, any item or service for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician.

(ii) Except as provided in paragraph (2) of this definition, a request by a physician that includes the provision of laboratory services or the establishment of a plan of care by a physician that includes the provision of laboratory services.

(2) Does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services if—

(i) The request is part of a consultation initiated by another physician; and

(ii) The tests or services are furnished by or under the supervision of the pathologist.

Referring physician means a physician (or group practice) who makes a referral as defined in this section.

Remuneration means any payment, discount, forgiveness of debt, or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration:

(1) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.

(2) The furnishing of items, devices, or supplies that are used solely to collect, transport, process, or store specimens for the entity furnishing the items, devices, or supplies or are used solely to order or communicate the results of tests or procedures for the entity.

(3) A payment made by an insurer or a self-insured plan to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if—

(i) The health services are not furnished, and the payment is not made, under a contract or other arrangement between the insurer or the plan and the physician;

(ii) The payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual; and

(iii) The amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals.

Transaction means an instance or process of two or more persons doing business. An *isolated transaction* is one involving a single payment between two or more persons. A transaction that involves long-term or installment payments is not considered an isolated transaction.

§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.

(a) *Prohibition on referrals.* Except as provided in this subpart, a physician

who has a financial relationship with an entity, or who has an immediate family member who has a financial relationship with the entity, may not make a referral to that entity for the furnishing of clinical laboratory services for which payment otherwise may be made under Medicare.

(b) *Limitations on billing.* An entity that furnishes clinical laboratory services under a referral that is prohibited by paragraph (a) of this section may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the clinical laboratory services performed under that referral.

(c) *Denial of payment.* No Medicare payment may be made for a clinical laboratory service that is furnished under a prohibited referral.

(d) *Refunds.* An entity that collects payment for a laboratory service that was performed under a prohibited referral must refund all collected amounts on a timely basis.

§ 411.355 General exceptions to referral prohibitions related to both ownership/investment and compensation.

The prohibition on referrals set forth in § 411.353 does not apply to the following types of services:

(a) *Physicians' services,* as defined in § 410.20(a), that are furnished personally by (or under the personal supervision of) another physician in the same group practice as the referring physician.

(b) *In-office ancillary services.* Services that meet the following conditions:

(1) They are furnished personally by one of the following individuals:

(i) The referring physician.

(ii) A physician who is a member of the same group practice as the referring physician.

(iii) Individuals who are directly supervised by the referring physician or, in the case of group practices, by another physician in the same group practice as the referring physician.

(2) They are furnished in one of the following locations:

(i) A building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of clinical laboratory services.

(ii) A building that is used by the group practice for the provision of some or all of the group's clinical laboratory services.

(3) They are billed by one of the following:

(i) The physician performing or supervising the service.

(ii) The group practice of which the performing or supervising physician is a member.

(iii) An entity that is wholly owned by the physician or the physician's group practice.

(c) *Services furnished to prepaid health plan enrollees by one of the following organizations:*

(1) An HMO or a CMP in accordance with a contract with HCFA under section 1876 of the Act and part 417, subparts J through M, of this chapter.

(2) A health care prepayment plan in accordance with an agreement with HCFA under section 1833(a)(1)(A) of the Act and part 417, subpart U, of this chapter.

(3) An organization that is receiving payments on a prepaid basis for the enrollees through a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b–1 note).

(4) A qualified health maintenance organization (within the meaning of section 1310(d) of the Public Health Service Act).

(d) *Services furnished in an ambulatory surgical center (ASC) or end stage renal disease (ESRD) facility, or by a hospice* if payment for those services is included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice charge, respectively.

§ 411.356 Exceptions to referral prohibitions related to ownership or investment interests.

For purposes of § 411.353, the following ownership or investment interests do not constitute a financial relationship:

(a) *Publicly traded securities.* Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that may be